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and Axsome Therapeutics, Inc.*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

**AXSOME MALTA LTD. and AXSOME  
THERAPEUTICS, INC.,**

**Plaintiffs,**

**v.**

**ALKEM LABORATORIES LTD.,  
AUROBINDO PHARMA USA, INC.,  
HETERO USA INC., HETERO LABS  
LIMITED UNIT-V, HETERO LABS LTD.,  
HIKMA PHARMACEUTICALS USA  
INC., SANDOZ INC., and UNICHEM  
LABORATORIES LTD.,**

**Defendants.**

**Civil Action No. 23-20354 (MCA)(JBC)**

**(Filed Electronically)**

**PLAINTIFFS' ANSWER TO HETERO USA INC., HETERO LABS LIMITED UNIT-V,  
AND HETERO LABS LTD.'S COUNTERCLAIMS**

Plaintiffs Axsome Malta Ltd. and Axsome Therapeutics, Inc. (together, “Axsome”), by their undersigned attorneys, hereby answer the Counterclaims to their Complaint for Patent Infringement by Defendants Hetero USA Inc., Hetero Labs Limited Unit-V, and Hetero Labs Ltd. (collectively, “Hetero” or “Defendants”), dated November 17, 2023 (the “Counterclaims”), as follows. Except as expressly admitted, all allegations are denied.

**HETERO'S COUNTERCLAIMS**

**PARTIES**

1. Hetero USA Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, NJ 08854.

**ANSWER:** Axsome admits on information and belief the allegations of paragraph 1.

2. Hetero Labs Limited Unit-V is a corporation organized and existing under the laws of India, having a principal place of business at Polepally, Jadcherla, Mahabubnagar – 509301, Andhra Pradesh, India.

**ANSWER:** Axsome admits on information and belief the allegations of paragraph 2.

3. Hetero Labs Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Andhra Pradesh, India.

**ANSWER:** Axsome admits on information and belief the allegations of paragraph 3.

4. On information and belief, Axsome Malta Ltd. is a corporation organized and existing under the laws of the Republic of Malta, having a principal place of business at 78 Mill Street, Zone 5, Central Business District, Qormi, CBD 5090, Malta.

**ANSWER:** Axsome admits that Axsome Malta Ltd. is a corporation organized and existing under the laws of the Republic of Malta, but denies paragraph 4 concerning the principal place of business. The principal place of business for Axsome Malta Ltd. has changed to Pinto Business Centre, Level 4, Office 4, Mill Street, Qormi, Triq il-Mithna Hal, Malta, QRM 3104.

5. On information and belief, Axsome Therapeutics, Inc., is a corporation organized and existing under the laws of Delaware, having a principal place of business at One World Trade Center, 22nd Floor, New York, New York 10007.

**ANSWER:** Axsome admits the allegations of paragraph 5.

**JURISDICTION AND VENUE**

6. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202; based on an actual controversy between Hetero, on the one hand, and Axsome on the other hand, arising under the Patent Laws of the United States, 35 U.S.C. §§ 1 et seq.

**ANSWER:** Paragraph 6 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that this Court has subject matter jurisdiction over Hetero's counterclaims as to United States Patent Nos. 8,440,715 ('the '715 patent'), 10,195,151 ('the '151 patent'), 10,512,609 ('the '609 patent'), 11,439,597 ('the '597 patent'), 10,912,754 ('the '754 patent'), 10,959,976 ('the '976 patent'), 11,160,779 ('the '779 patent'), 10,940,133 ('the '133 patent'), 11,560,354 ('the '354 patent'), and 11,648,232 ('the '232 patent') (collectively, "the patents-in-suit against Hetero"), admits that there is a justiciable controversy between Axsome and Hetero regarding the patents-in-suit against Hetero, but denies that Hetero is entitled to any of the relief that it seeks, and, except as so admitted, denies the allegations of paragraph 6.

7. This Court has personal jurisdiction over Axsome because, *inter alia*, Axsome subjected itself to the jurisdiction of this Court by filing its Complaint here.

**ANSWER:** Paragraph 7 states a legal conclusion for which no answer is required. To the extent that an answer is required, Axsome admits that this Court has personal jurisdiction over Axsome for purposes of this action only, but denies that Hetero is entitled to any of the relief that it seeks, and, except as so admitted, denies the allegations of paragraph 7.

8. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b), and/or by Axsome's choice of forum.

**ANSWER:** Paragraph 8 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that venue is proper to adjudicate this action and, except as so admitted, denies the allegations of paragraph 8.

### **FACTUAL BACKGROUND**

9. On information and belief, and based on the allegations in the Complaint, Axsome is the holder of New Drug Application ("NDA") No. 211230 for solriamfetol oral tablets, Eq. 75 mg base and Eq. 150 mg base, which is sold under trade name Sunosi®.

**ANSWER:** Axsome admits that it is the holder of NDA No. 211230 for solriamfetol oral tablets, Eq. 75 mg base and Eq. 150 mg base, which is sold under the trademark Sunosi® and, except as so admitted, denies the allegations of paragraph 9.

10. On information and belief, and based on the allegations in the Complaint, Axsome caused the Food and Drug Administration (“FDA”) to list U.S. Patent Nos. 8,440,715 (“the ‘715 patent”), 10,195,151 (“the ‘151 patent”), 10,512,609 (“the ‘609 patent”), 11,439,597 (“the ‘597 patent”), 10,912,754 (“the ‘754 patent”), 10,959,976 (“the ‘976 patent”), 11,160,779 (“the ‘779 patent”), 10,940,133 (“the ‘133 patent”), 11,560,354 (“the ‘354 patent”), and 11,648,232 (“the ‘232 patent”) (collectively, “the Asserted Patents”) in the FDA’s publication Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”) in connection with NDA No. 211230.

**ANSWER:** Axsome admits that it submitted the patents-in-suit against Hetero to the FDA for listing in the Orange Book in connection with NDA No. 211230, and, except as so admitted, denies the allegations of paragraph 10.

11. The ‘715 patent lists the title as “Treatment of Sleep-wake Disorders,” and the issue date as May 14, 2013.

**ANSWER:** Axsome admits the allegations of paragraph 11.

12. The ‘151 patent lists the title as “Formulations of (R)-2-amino-3-phenylpropyl carbamate,” and the issue date as February 5, 2019.

**ANSWER:** Axsome admits the allegations of paragraph 12.

13. The ‘609 patent lists the title as “Formulations of (R)-2-amino-3-phenylpropyl carbamate,” and the issue date as December 24, 2019.

**ANSWER:** Axsome admits the allegations of paragraph 13.

14. The ‘597 patent lists the title as “Formulations of (R)-2-amino-3-phenylpropyl carbamate,” and the issue date as September 13, 2022.

**ANSWER:** Axsome admits the allegations of paragraph 14.

15. The ‘754 patent lists the title as “Methods and Compositions for Treating Excessive Sleepiness,” and the issue date as February 9, 2021.

**ANSWER:** Axsome admits the allegations of paragraph 15.

16. The '976 patent lists the title as "Methods and Compositions for Treating Excessive Sleepiness," and the issue date as March 30, 2021.

**ANSWER:** Axsome admits the allegations of paragraph 16.

17. The '779 patent lists the title as "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function," and the issue date as November 2, 2021.

**ANSWER:** Axsome admits the allegations of paragraph 17.

18. The '133 patent lists the title as "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function," and the issue date as March 9, 2021.

**ANSWER:** Axsome admits the allegations of paragraph 18.

19. The '354 patent lists the title as "Compositions comprising (R)-2-amino-3-phenylpropyl carbamate and uses thereof," and the issue date as January 24, 2023.

**ANSWER:** Axsome admits the allegations of paragraph 19.

20. The '232 patent lists the title as "Methods and Compositions for Treating Excessive Sleepiness," and the issue date as May 16, 2023.

**ANSWER:** Axsome admits the allegations of paragraph 20.

21. Axsome purports and claims to be the owner of or exclusive licensee for, and to have the right to enforce, the Asserted Patents.

**ANSWER:** Axsome admits the allegations of paragraph 21.

22. Hetero submitted Abbreviated New Drug Application ("ANDA") No. 218654 to the FDA under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, importation, offer for sale or sale of Hetero's proposed drug product containing solriamfetol oral tablets, Eq. 75 mg base and Eq. 150 mg base ("Hetero's ANDA product"). Hetero submitted ANDA No. 218654 to the FDA with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '715 patent, the '151 patent, the '609 patent, the '597 patent, the '754 patent, the '976 patent, the '779 patent, the '133 patent, the '354 patent, and the '232 patent.

**ANSWER:** Axsome admits on information and belief that Hetero submitted Abbreviated New Drug Application ("ANDA") No. 218654 ("Hetero's ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of a generic version of Axsome's solriamfetol oral tablets drug products prior to the expiration of the patents-

in-suit against Hetero. Axsome further admits on information and belief that, in connection with the submission of its ANDA as described above, Hetero provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Hetero’s Paragraph IV Certification”), alleging that the claims of the patents-in-suit against Hetero are invalid and/or will not be infringed by the activities described in Hetero’s ANDA, but Axsome denies the legitimacy of Hetero’s allegations. Except as so admitted, Axsome denies the allegations of paragraph 22.

23. Hetero sent notice of this certification to Axsome on or about August 15, 2023 (“the Notice Letter”). On information and belief, and as Axsome alleges in its Complaint, Axsome received the Notice Letter.

**ANSWER:** Axsome admits that no earlier than August 15, 2023, Hetero sent a written notice of Hetero’s Paragraph IV Certification to Axsome (“Hetero’s August 15 Notice Letter”) and that Axsome received Hetero’s August 15 Notice Letter at a later point in time, and, except as so admitted, denies the allegations of paragraph 23.

24. On September 13, 2023, Axsome filed suit in this Judicial District against Hetero in connection with ANDA No. 218654 alleging infringement of the Asserted Patents.

**ANSWER:** Axsome admits that, on September 13, 2023, it filed the Complaint in the above-captioned litigation alleging, inter alia, Hetero’s infringement of the patents-in-suit against Hetero, including that Hetero has infringed and will infringe the patents-in-suit against Hetero by submitting ANDA No. 218654 and by making, using, offering to sell, selling, and/or importing in to the United States Hetero’s Proposed Product, and, except as so admitted, denies the allegations of paragraph 24.

25. In view of the foregoing, there has been, and is now, an actual, substantial, and continuing, justiciable controversy between Hetero and Axsome having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court with respect to noninfringement and/or invalidity of the Asserted Patents, and as to Hetero’s right to obtain FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Hetero’s ANDA product.

**ANSWER:** Paragraph 25 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that there is an actual and justiciable controversy between Hetero and Axsome regarding the patents-in-suit against Hetero, and, except as so admitted, denies the allegations of paragraph 25.

**Count I: Declaratory Judgment of Alleged Non-Infringement of the '715 Patent**

26. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

**ANSWER:** Axsome incorporates its answers to the preceding paragraphs as if fully set forth herein.

27. Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '715 patent.

**ANSWER:** Axsome denies the allegations of paragraph 27.

28. A present, genuine, and justiciable controversy exists between Hetero, on the one hand, and Axsome, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Hetero's ANDA Product would infringe any valid or enforceable claim of the '715 patent.

**ANSWER:** Paragraph 28 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that there is a justiciable controversy between Axsome and Hetero regarding the '715 patent, and, except as so admitted, denies the allegations of paragraph 28.

29. The Court should declare that Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '715 patent.

**ANSWER:** Axsome denies the allegations of paragraph 29.

**Count II: Declaratory Judgment of Alleged Invalidity of the '715 Patent**

30. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

**ANSWER:** Axsome incorporates its answers to the preceding paragraphs as if fully set forth herein.

31. In accordance with 21 U.S.C. § 355(j)(2)(B), the Notice Letter included a detailed statement of factual and legal bases for why one or more claims of the '715 patent are invalid.

**ANSWER:** Axsome denies the allegations of paragraph 31.

32. Upon information and belief, the claims of the '715 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 et seq., and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially-created and/or non-statutory basis for invalidity or unenforceability.

**ANSWER:** Axsome denies the allegations of paragraph 32.

33. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '715 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

**ANSWER:** Paragraph 33 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that there is a justiciable controversy between Axsome and Hetero regarding the '715 patent, and, except as so admitted, denies the allegations of paragraph 33.

34. The Court should declare that the claims of the '715 patent are invalid and/or unenforceable.

**ANSWER:** Axsome denies the allegations of paragraph 34.

**Count III: Declaratory Judgment of Alleged Non-Infringement of the '151 Patent**

35. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

**ANSWER:** Axsome incorporates its answers to the preceding paragraphs as if fully set forth herein.

36. Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '151 patent.

**ANSWER:** Axsome denies the allegations of paragraph 36.

37. A present, genuine, and justiciable controversy exists between Hetero, on the one hand, and Axsome, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Hetero's ANDA Product would infringe any valid or enforceable claim of the '151 patent.

**ANSWER:** Paragraph 37 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that there is a justiciable controversy between Axsome and Hetero regarding the '151 patent, and, except as so admitted, denies the allegations of paragraph 37.

38. The Court should declare that Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '151 patent.

**ANSWER:** Axsome denies the allegations of paragraph 38.

#### **Count IV: Declaratory Judgment of Alleged Invalidity of the '151 Patent**

39. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

**ANSWER:** Axsome incorporates its answers to the preceding paragraphs as if fully set forth herein.

40. Upon information and belief, the claims of the '151 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially-created and/or non-statutory basis for invalidity or unenforceability.

**ANSWER:** Axsome denies the allegations of paragraph 40.

41. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '151 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

**ANSWER:** Paragraph 41 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that there is a justiciable controversy between Axsome and Hetero regarding the '151 patent, and, except as so admitted, denies the allegations of paragraph 41.

42. The Court should declare that the claims of the '151 patent are invalid and/or unenforceable.

**ANSWER:** Axsome denies the allegations of paragraph 42.

**Count V: Declaratory Judgment of Alleged Non-Infringement of the '609 Patent**

43. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

**ANSWER:** Axsome incorporates its answers to the preceding paragraphs as if fully set forth herein.

44. Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '609 patent.

**ANSWER:** Axsome denies the allegations of paragraph 44.

45. A present, genuine, and justiciable controversy exists between Hetero, on the one hand, and Axsome, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Hetero's ANDA Product would infringe any valid or enforceable claim of the '609 patent.

**ANSWER:** Paragraph 45 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that there is a justiciable controversy between Axsome and Hetero regarding the '609 patent, and, except as so admitted, denies the allegations of paragraph 45.

46. The Court should declare that Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '609 patent.

**ANSWER:** Axsome denies the allegations of paragraph 46.

**Count VI: Declaratory Judgment of Alleged Invalidity of the '609 Patent**

47. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

**ANSWER:** Axsome incorporates its answers to the preceding paragraphs as if fully set forth herein.

48. Upon information and belief, the claims of the '609 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 et seq., and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially-created and/or non-statutory basis for invalidity or unenforceability.

**ANSWER:** Axsome denies the allegations of paragraph 48.

49. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '609 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

**ANSWER:** Paragraph 49 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that there is a justiciable controversy between Axsome and Hetero regarding the '609 patent, and, except as so admitted, denies the allegations of paragraph 49.

50. The Court should declare that the claims of the '609 patent are invalid and/or unenforceable.

**ANSWER:** Axsome denies the allegations of paragraph 50.

**Count VII: Declaratory Judgment of Alleged Non-Infringement of the '597 Patent**

51. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

**ANSWER:** Axsome incorporates its answers to the preceding paragraphs as if fully set forth herein.

52. Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '597 patent.

**ANSWER:** Axsome denies the allegations of paragraph 52.

53. A present, genuine, and justiciable controversy exists between Hetero, on the one hand, and Axsome, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Hetero's ANDA Product would infringe any valid or enforceable claim of the '597 patent.

**ANSWER:** Paragraph 53 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that there is a justiciable controversy between Axsome and Hetero regarding the '597 patent, and, except as so admitted, denies the allegations of paragraph 53.

54. The Court should declare that Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '597 patent.

**ANSWER:** Axsome denies the allegations of paragraph 54.

**Count VIII: Declaratory Judgment of Alleged Invalidity of the '597 Patent**

55. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

**ANSWER:** Axsome incorporates its answers to the preceding paragraphs as if fully set forth herein.

56. Upon information and belief, the claims of the '597 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112,

and/or 251 et seq., and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially-created and/or non-statutory basis for invalidity or unenforceability.

**ANSWER:** Axsome denies the allegations of paragraph 56.

57. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '597 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

**ANSWER:** Paragraph 57 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that there is a justiciable controversy between Axsome and Hetero regarding the '597 patent, and, except as so admitted, denies the allegations of paragraph 57.

58. The Court should declare that the claims of the '597 patent are invalid and/or unenforceable.

**ANSWER:** Axsome denies the allegations of paragraph 58.

**Count IX: Declaratory Judgment of Alleged Non-Infringement of the '754 Patent**

59. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

**ANSWER:** Axsome incorporates its answers to the preceding paragraphs as if fully set forth herein.

60. Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '754 patent.

**ANSWER:** Axsome denies the allegations of paragraph 60.

61. A present, genuine, and justiciable controversy exists between Hetero, on the one hand, and Axsome, on the other hand, regarding, inter alia, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Hetero's ANDA Product would infringe any valid or enforceable claim of the '754 patent.

**ANSWER:** Paragraph 61 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that there is a justiciable controversy between Axsome and Hetero regarding the '754 patent, and, except as so admitted, denies the allegations of paragraph 61.

62. The Court should declare that Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '754 patent.

**ANSWER:** Axsome denies the allegations of paragraph 62.

**Count X: Declaratory Judgment of Alleged Invalidity of the '754 Patent**

63. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

**ANSWER:** Axsome incorporates its answers to the preceding paragraphs as if fully set forth herein.

64. In accordance with 21 U.S.C. § 355(j)(2)(B), the Notice Letter included a detailed statement of factual and legal bases for why one or more claims of the '754 patent are invalid.

**ANSWER:** Axsome denies the allegations of paragraph 64.

65. Upon information and belief, the claims of the '754 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 et seq., and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially-created and/or non-statutory basis for invalidity or unenforceability.

**ANSWER:** Axsome denies the allegations of paragraph 65.

66. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '754 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

**ANSWER:** Paragraph 66 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that there is a justiciable controversy

between Axsome and Hetero regarding the '754 patent, and, except as so admitted, denies the allegations of paragraph 66.

67. The Court should declare that the claims of the '754 patent are invalid and/or unenforceable.

**ANSWER:** Axsome denies the allegations of paragraph 67.

**Count XI: Declaratory Judgment of Alleged Non-Infringement of the '976 Patent**

68. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

**ANSWER:** Axsome incorporates its answers to the preceding paragraphs as if fully set forth herein.

69. Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '976 patent.

**ANSWER:** Axsome denies the allegations of paragraph 69.

70. A present, genuine, and justiciable controversy exists between Hetero, on the one hand, and Axsome, on the other hand, regarding, inter alia, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Hetero's ANDA Product would infringe any valid or enforceable claim of the '976 patent.

**ANSWER:** Paragraph 70 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that there is a justiciable controversy between Axsome and Hetero regarding the '976 patent, and, except as so admitted, denies the allegations of paragraph 70.

71. The Court should declare that Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '976 patent.

**ANSWER:** Axsome denies the allegations of paragraph 71.

**Count XII: Declaratory Judgment of Alleged Invalidity of the '976 Patent**

72. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

**ANSWER:** Axsome incorporates its answers to the preceding paragraphs as if fully set forth herein.

73. In accordance with 21 U.S.C. § 355(j)(2)(B), the Notice Letter included a detailed statement of factual and legal bases for why one or more claims of the '976 patent are invalid.

**ANSWER:** Axsome denies the allegations of paragraph 73.

74. Upon information and belief, the claims of the '976 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 et seq., and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially-created and/or non-statutory basis for invalidity or unenforceability.

**ANSWER:** Axsome denies the allegations of paragraph 74.

75. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '976 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

**ANSWER:** Paragraph 75 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that there is a justiciable controversy between Axsome and Hetero regarding the '976 patent, and, except as so admitted, denies the allegations of paragraph 75.

76. The Court should declare that the claims of the '976 patent are invalid and/or unenforceable.

**ANSWER:** Axsome denies the allegations of paragraph 76.

**Count XIII: Declaratory Judgment of Alleged Non-Infringement of the '779 Patent**

77. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

**ANSWER:** Axsome incorporates its answers to the preceding paragraphs as if fully set forth herein.

78. Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '779 patent.

**ANSWER:** Axsome denies the allegations of paragraph 78.

79. A present, genuine, and justiciable controversy exists between Hetero, on the one hand, and Axsome, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Hetero's ANDA Product would infringe any valid or enforceable claim of the '779 patent.

**ANSWER:** Paragraph 79 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that there is a justiciable controversy between Axsome and Hetero regarding the '779 patent, and, except as so admitted, denies the allegations of paragraph 79.

80. The Court should declare that Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '779 patent.

**ANSWER:** Axsome denies the allegations of paragraph 80.

#### **Count XIV: Declaratory Judgment of Alleged Invalidity of the '779 Patent**

81. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

**ANSWER:** Axsome incorporates its answers to the preceding paragraphs as if fully set forth herein.

82. In accordance with 21 U.S.C. § 355(j)(2)(B), the Notice Letter included a detailed statement of factual and legal bases for why one or more claims of the '779 patent are invalid.

**ANSWER:** Axsome denies the allegations of paragraph 82.

83. Upon information and belief, the claims of the '779 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting,

and/or for any other judicially-created and/or non-statutory basis for invalidity or unenforceability.

**ANSWER:** Axsome denies the allegations of paragraph 83.

84. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '779 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

**ANSWER:** Paragraph 84 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that there is a justiciable controversy between Axsome and Hetero regarding the '779 patent, and, except as so admitted, denies the allegations of paragraph 84.

85. The Court should declare that the claims of the '779 patent are invalid and/or unenforceable.

**ANSWER:** Axsome denies the allegations of paragraph 85.

**Count XV: Declaratory Judgment of Alleged Non-Infringement of the '133 Patent**

86. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

**ANSWER:** Axsome incorporates its answers to the preceding paragraphs as if fully set forth herein.

87. Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '133 patent.

**ANSWER:** Axsome denies the allegations of paragraph 87.

88. A present, genuine, and justiciable controversy exists between Hetero, on the one hand, and Axsome, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Hetero's ANDA Product would infringe any valid or enforceable claim of the '133 patent.

**ANSWER:** Paragraph 88 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that there is a justiciable controversy between Axsome and Hetero regarding the '133 patent, and, except as so admitted, denies the allegations of paragraph 88.

89. The Court should declare that Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '133 patent.

**ANSWER:** Axsome denies the allegations of paragraph 89.

**Count XVI: Declaratory Judgment of Alleged Invalidity of the '133 Patent**

90. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

**ANSWER:** Axsome incorporates its answers to the preceding paragraphs as if fully set forth herein.

91. In accordance with 21 U.S.C. § 355(j)(2)(B), the Notice Letter included a detailed statement of factual and legal bases for why one or more claims of the '133 patent are invalid.

**ANSWER:** Axsome denies the allegations of paragraph 91.

92. Upon information and belief, the claims of the '133 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 et seq., and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially-created and/or non-statutory basis for invalidity or unenforceability.

**ANSWER:** Axsome denies the allegations of paragraph 92.

93. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '133 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

**ANSWER:** Paragraph 93 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that there is a justiciable controversy

between Axsome and Hetero regarding the '133 patent, and, except as so admitted, denies the allegations of paragraph 93.

94. The Court should declare that the claims of the '133 patent are invalid and/or unenforceable.

**ANSWER:** Axsome denies the allegations of paragraph 94.

**Count XVII: Declaratory Judgment of Alleged Non-Infringement of the '354 Patent**

95. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

**ANSWER:** Axsome incorporates its answers to the preceding paragraphs as if fully set forth herein.

96. Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '354 patent.

**ANSWER:** Axsome denies the allegations of paragraph 96.

97. A present, genuine, and justiciable controversy exists between Hetero, on the one hand, and Axsome, on the other hand, regarding, inter alia, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Hetero's ANDA Product would infringe any valid or enforceable claim of the '354 patent.

**ANSWER:** Paragraph 97 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that there is a justiciable controversy between Axsome and Hetero regarding the '354 patent, and, except as so admitted, denies the allegations of paragraph 97.

98. The Court should declare that Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '354 patent.

**ANSWER:** Axsome denies the allegations of paragraph 98.

**Count XVIII: Declaratory Judgment of Alleged Invalidity of the '354 Patent**

99. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

**ANSWER:** Axsome incorporates its answers to the preceding paragraphs as if fully set forth herein.

100. In accordance with 21 U.S.C. § 355(j)(2)(B), the Notice Letter included a detailed statement of factual and legal bases for why one or more claims of the '354 patent are invalid.

**ANSWER:** Axsome denies the allegations of paragraph 100.

101. Upon information and belief, the claims of the '354 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 et seq., and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially-created and/or non-statutory basis for invalidity or unenforceability.

**ANSWER:** Axsome denies the allegations of paragraph 101.

102. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '354 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

**ANSWER:** Paragraph 102 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that there is a justiciable controversy between Axsome and Hetero regarding the '354 patent, and, except as so admitted, denies the allegations of paragraph 102.

103. The Court should declare that the claims of the '354 patent are invalid and/or unenforceable.

**ANSWER:** Axsome denies the allegations of paragraph 103.

**Count XIX: Declaratory Judgment of Alleged Non-Infringement of the '232 Patent**

104. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

**ANSWER:** Axsome incorporates its answers to the preceding paragraphs as if fully set forth herein.

105. Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '232 patent.

**ANSWER:** Axsome denies the allegations of paragraph 105.

106. A present, genuine, and justiciable controversy exists between Hetero, on the one hand, and Axsome, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Hetero's ANDA Product would infringe any valid or enforceable claim of the '232 patent.

**ANSWER:** Paragraph 106 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that there is a justiciable controversy between Axsome and Hetero regarding the '232 patent, and, except as so admitted, denies the allegations of paragraph 106.

107. The Court should declare that Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '232 patent.

**ANSWER:** Axsome denies the allegations of paragraph 107.

#### **Count XX: Declaratory Judgment of Alleged Invalidity of the '232 Patent**

108. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

**ANSWER:** Axsome incorporates its answers to the preceding paragraphs as if fully set forth herein.

109. In accordance with 21 U.S.C. § 355(j)(2)(B), the Notice Letter included a detailed statement of factual and legal bases for why one or more claims of the '232 patent are invalid.

**ANSWER:** Axsome denies the allegations of paragraph 109.

110. Upon information and belief, the claims of the '232 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting,

and/or for any other judicially-created and/or non-statutory basis for invalidity or unenforceability.

**ANSWER:** Axsome denies the allegations of paragraph 110.

111. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '232 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

**ANSWER:** Paragraph 111 states legal conclusions for which no answer is required. To the extent that an answer is required, Axsome admits that there is a justiciable controversy between Axsome and Hetero regarding the '232 patent, and, except as so admitted, denies the allegations of paragraph 111.

112. The Court should declare that the claims of the '232 patent are invalid and/or unenforceable.

**ANSWER:** Axsome denies the allegations of paragraph 112.

#### **HETERO'S PRAYER FOR RELIEF**

Axsome denies that Hetero is entitled to any relief on its Counterclaims, either as prayed for in its pleading or otherwise.

#### **AXSOME'S AFFIRMATIVE DEFENSE**

Without prejudice to the denials set forth in this Answer and to the ability to amend this Answer to seek and allege any and all defenses not presently known or that are revealed during the course of discovery or otherwise, Axsome asserts the following affirmative defense in response to Hetero's Counterclaims:

#### **Failure to State a Claim**

The Counterclaims fail to state any claim for which relief may be granted.

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